1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (5 ml) contains:

Active substances:

Inactivated Bovine Respiratory Syncytial virus, strain EV908	$10^{4.77} – 10^{5.45}$	U/dose*
Inactivated Parainfluenza-3Virus, strain SF-4 Reisinger	$10^{3.54} – 10^{4.85}$	U/dose*
Inactivated *Mannheimia haemolytica* A1, strain M4/1	$10^{4.24} – 10^{5.00}$	U/dose*

* Results obtained with AlphaLISA assays

Adjuvants:

Aluminium hydroxide	37.5 mg
Quil A (Saponin)	0.189 – 0.791 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.032 – 0.058 mg
Simethicone	
Formaldehyde	

Pale yellow to red-pink with whitish sediment. By shaking the sediment is easily suspended to an opaque, whitish to red/pink suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the active immunisation of cattle against:
- Parainfluenza-3 virus, to reduce infection,
- Bovine Respiratory Syncytial virus, to reduce infection and clinical signs,
- *Mannheimia haemolytica* serotype A1, to reduce infection, mortality, clinical signs, lung lesions and bacterial invasion of the lung caused by serotypes A1 and A6.

Cross-reactive immunity to the A6 serotype of *Mannheimia haemolytica* has been demonstrated in a challenge experiment under laboratory conditions after primary course of vaccination.
Approximately two weeks after completion of the basic immunisation programme, the humoral immune response against Bovine Respiratory Syncytial virus and Parainfluenza-3 virus is at its highest level. The duration of protective immunity has not been established in challenge experiments.

Onset of immunity: 2 weeks.

Duration of immunity: has not been established.

3.3 Contraindications

Do not vaccinate animals that have intercurrent disease, heavy parasitic infestation or are in poor general condition, since a satisfactory immune response will only be obtained in healthy and immuno-competent animals.

3.4 Special warnings

Vaccinate healthy animals only.

The basic immunisation should be started in time, so that immunity has fully developed by the beginning of the period of risk. The basic immunisation of calves should be completed prior to housing or should be performed in the housing unit under quarantine.

It is advisable to vaccinate all animals in a herd in order to minimise the infectious potential unless there is a contraindication. Failure to vaccinate individual animals may promote the transmission of pathogens and development of disease.

The magnitude of the antibody response may be reduced by maternally derived antibodies in calves up to six weeks of age. However, according to the results of challenge experiments, significant protection against infection by Bovine Respiratory Syncytial virus is still provided three weeks after the basic vaccination course, and significant protection against Parainfluenza-3 virus and *Mannheimia haemolytica* serotype A1 is still provided six weeks after the basic vaccination course. The results of challenge experiments in calves with maternally derived antibodies further indicate that the onset of cross-protective immunity to the A6 serotype is 2 weeks after completion of the vaccination course. Cross protective immunity is provided up to six weeks after the basic vaccination course as demonstrated by serological tests.

Respiratory infections in calves are often associated with poor hygiene. Thus, general improvements in hygiene are important to support the effect of vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]. Elevated temperature[2], reluctant to move.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[3].

[1] In extreme cases narrow swellings up to 10 cm long. Typically, these swellings completely disappear or reduce in size to a negligible small lump within 2 to 3 weeks after vaccination, though in individual animals very small reactions can be found for up to 3 months.
[2] Slight and lasting a maximum of 3 days after vaccination.
[3] May be fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis IBR Marker Live (where this product is authorised) in cattle from 3 weeks of age onwards.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Immunosuppressive drugs should generally not be used directly before or after vaccination, since a satisfactory immune response will only be obtained in immuno-competent animals.

3.9 Administration routes and dosage

Method of administration:
Subcutaneous use. Injection into the side of the neck.

Dose:
5 ml.

Basic immunisation:
Animals from approximately 2 weeks of age should receive two vaccinations separated by an interval of approximately 4 weeks.

Booster doses:
If booster doses are required, a single dose should be given approximately 2 weeks before each risk period (e.g. transport, introduction into a herd, change of housing).

The vaccine must be shaken well before use.

For vaccine administration, needles of 1.5 to 2.0 mm diameter and 10 to 18 mm long are recommended. The vaccine should be brought to room temperature prior to use and injected quickly.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdosage is unlikely to cause any reaction other than described in section 3.6, however the swelling may be larger and temperature rise may be higher.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AL04.

The vaccine contains as active ingredients inactivated Bovine Respiratory Syncytial virus (strain EV 908) and Parainfluenza-3 virus (strain SF-4 Reisinger) as well as inactivated *Mannheimia haemolytica* bacteria (serotype A1) propagated under conditions of iron restriction. Aluminium hydroxide and Quil A are included as adjuvants. Thiomersal serves as preservative.

The vaccine induces antibodies against Bovine Respiratory Syncytial virus, Parainfluenza-3 virus and *Mannheimia haemolytica.*

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 28 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from frost.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box with 50 ml bottles of type I glass (10 doses), closed with injection stoppers type I rubber sealed with an aluminium crimp cap.

Pack size:
Cardboard box with 1 glass bottle of 50 ml (10 doses).

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/152/001

8. DATE OF FIRST AUTHORISATION

06/06/2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/08/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).